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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,559	10/27/2003	Robert F. Kaiko	200.1102CON3	2420

7590 03/30/2006

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,559	KAIKO ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7,8,10-16,18-20,36-41,43,44,52-54 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7,8,10-16,18-20,36-41,43,44,52-54 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/13/06 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 7, 8, 11-16, 18-20 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-16 and 18-20 of U.S. Patent No. 6,475,494 ('494). Although the conflicting claims are not identical, they are not patentably distinct from each other because '494 claims an oral dosage form comprising the claimed combination of an opioid agonist and an opioid antagonist agents in the claimed ratios (claims 1, 4, 5, 12-16 and 18-20). The dosage form further comprises non-opioid drug, excipient, and sustained release carrier (claims 7, 8 and 11). Therefore, one of ordinary skill in the art would expect the same composition results from the use of the instant invention given the claims of '494. There are no unusual and/or unexpected results, which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of '494, which set out a similar composition as claimed herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 8, 10, 11, 13, 18, 20, 36-41, 43 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crain et al. US 5,580,876 (Crain 1), in view of Crain et al. US 5,512,578 (Crain 2).

Crain 1 teaches a composition comprising an opioid agonist such as morphine, codeine, or methadone in combination with an opioid antagonist such as naltrexone in an oral dosage form (column 2, lines 38-45; column 4, lines 34-36, 64-67; and column 5, lines 11-15). The opioid agonist and antagonist may be used in the form of free bases or pharmaceutically acceptable acid salts such as hydrochloric (column 5, lines 1-6). The composition further comprises pharmaceutically acceptable carrier and additives (column 5, lines 23-47). Crain 1 does not expressly teach the weight ratio of the opioid agonist and antagonist.

Crain 2 teaches orally administering combination of opioid agonist and antagonist in a weight ratio of about 0.01 to about 1 of opioid antagonist to opioid agonist (column 6, lines 9 through column 7, lines 1-5). Thus, it would have been obvious to one of ordinary skill in the art to prepare an oral dosage form of Crain 1 using the weight ratio opioid antagonist to opioid agonist in view of the teaching of Crain 2 to obtain the claimed invention, because Crain 1 teaches combination of opioid agonist and antagonist for the same purpose desired in Crain 2, namely, a method of selectively enhancing the analgesic potency of morphine and simultaneously attenuating development of physical dependence and/or tolerance effects associated with the

administration of opioid agonist (see abstracts), because Crain 1 teaches the amount of opioid agonist administered may be an analgesic or sub-analgesic amount (column 6, lines 6-49), and because Crain 2 teaches a sub-analgesic amount of opioid agonist (column 6, lines 9-67).

Claims 3, 5, 12, 14, 16, 19, 44, 52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crain et al. US 5,580,876 (Crain 1), in view of Crain et al. US 5,512,578 (Crain 2) and Kreek US 4,769,372.

Crain 1 and 2 are relied upon for the reason stated above. The references do not teach hydrocodone, oxycodone, hydromorphone, and meperidine.

Kreek teaches an oral composition comprising combination of opioid analgesic and opioid antagonist (abstract, and column 5, lines 38-46). The opioid analgesics (agonist) include hydrocodone, oxycodone, codeine, hydromorphone, meperidine, methadone, and morphine (column 4, lines 63-68). Opioid analgesic is administered from 1 to 5 times daily in an amount of from about 1.5 to about 100 mg (column 3, lines 10-60; and column 4, lines 63 through column 5, lines 1-15). Thus, it would have been obvious to one of ordinary skill in the art to use hydrocodone, oxycodone, hydromorphone, and meperidine as an opioid agonist in view of the teaching of Kreek to obtain the claimed invention, because Kreek teaches hydrocodone, oxycodone, codeine, morphine, hydromorphone, and meperidine are safe and effective for long term use, and because Crain 1 and 2 teach treating chronic pain using opioid compounds.

Claims 7, 15 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crain et al. US 5,580,876 (Crain 1), in view of Crain et al. US 5,512,578 (Crain 2) and Mitch et al. US 5,998,434.

Crain 1 and 2 are relied upon for the reason stated above. The references do not teach the additional non-opioid drug, and levorphanol as an opioid agonist.

Mitch teaches the use of opioid agonist such as morphine, codeine, hydromorphone or oxycodone, and levorphanol in combination of other medicines such as NSAID, or aspirin or acetaminophen for the treatment of chronic pain (columns 27 and 28). Thus, it would have been obvious to one of ordinary skill in the art to modify the teachings of Crain 1 and 2 using levorphanol as an opioid agonist, because Mitch teaches levorphanol is a well known opioid agonist in pharmaceutical art useful for the treatment of pain, and because Mitch teaches the use of combination of compounds having muscarinic activity are known to provide additive analgesic effects in man (ID).

Response to Arguments

Applicant's arguments filed 01/13/06, with respect to the 103(a) rejections of all claims have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of Crain 1 and 2.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Patent Examiner
Art Unit 1615